PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	24.04.2001
Applicant's or agent's file reference 110/01357	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL00/00056	27/01/2000	27/01/1999

Applicant
DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Ertl, L Tel.+49 89 2399-7447

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
110/01357		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL00/00056	27/01/2000	27/01/1999
International Patent Classification (IPC) or national classification and IPC A61F2/46		
Applicant DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28/08/2000	24.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Josten, S Telephone No. +49 89 2399 2338

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL00/00056

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-25	as originally filed				

Claims, No.:

9-99	as originally filed				
1-8	as received on	30/08/2000	with letter of	28/08/2000	

Drawings, sheets:

1/26-26/26	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 73-89.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 73-89.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☒ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-72, 90-99.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-72, 96
	No:	Claims	90, 91, 92, 94
Inventive step (IS)	Yes:	Claims	1-72, 96
	No:	Claims	93, 95, 97, 98, 99
Industrial applicability (IA)	Yes:	Claims	1-72, 90-99
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Claim 1 relates to an apparatus for controlling the deformation of an implant during deployment thereof. None of the documents cited in the search report discloses a force application mechanism for applying deforming force to the implant, by axial motion of a force applicator against the implant. The documents US-A-5759186 (=**D1**), US-A-5782838 and US-A-5683451 each describe self-expanding implants and there is therefore no need for applying a deforming force to the implant.

   Thus, claim 1 appears to meet the requirements of Articles 33(2) and 33(3) PCT.

2. Claims 2 to 72 are dependent from claim 1 and relate to preferred embodiments of the apparatus according to claim 1. Thus, claims 2 to 72 also appear to meet the requirements of Articles 33(2) and 33(3) PCT.

3. As to independent claim 90, the document US-A-5171248 (=**D2**) is considered to represent the closest prior art.

   D2 discloses (see figure 4) a measurment apparatus for taking measurements inside the body (see column 1, lines 56 to 58), comprising:
   a hollow tube 12, defining at least one slot 24, 26 at its end;
   a shaft 28 disposed within said tube 12; and
   at least one wing 32, 34 coupled to said shaft 28 and adapted to extend through said slot 24, 26, wherein an extension position of said wing 32, 34 determines an axial motion of said shaft in said tube,
   wherein said apparatus is adapted to come in contact with body fluids and wherein said apparatus is sterile.

   Thus, all features of claim 90 are known from **D2** and the claim, therefore, does not meet the requirements of Article 33(2) PCT.

4. The features of claims 91, 92, and 94 are also known from **D2**. Thus, claims 91,

92 and 94 do not meet the requirements of Article 33(2) PCT.

5. The features of claims 93, 95 and 97 to 99 cannot be seen as involving an inventive step since they relate to slight constructional changes of the apparatus known from **D2** which come within the scope of the customary practice followed by persons skilled in the art. Thus, claims 93, 95 and 97 to 99 do not meet the requirements of Article 33(3) PCT.

6. The features of claim 96 cannot be derived from the available documents. Thus, Claim 96 and claims being dependent therefrom appear to meet the requirements of Articles 33(2) and 33(3) PCT. However, reference is made to item VIII, paragraph 11.

Re Item VI
Certain documents cited

7. The priority 27.01.99 claimed by the present application has not been checked. The document WO-A-9939661 (filing date 05.02.99; priority date 05.02.98; publication date 12.08.99) is of particular relevance. The document WO-A-952446 (filing date 09.04.99; priority dates 09.04.98 and 27.10.98; publication date 21.10.99) is not considered to be of particular relevance.

Re Item VII
Certain defects in the international application

8. The application does not meet the requirements of Rule 6.3(b) PCT since the independent claims should have been properly cast in the two-part form, with those features which in combination are known from **D1** being placed in the preamble of claim 1 and with those features which in combination are known from **D2** being placed in the preamble of claim 90.

9. The application does not meet the requirements of Rule 6.2(b) PCT since reference signs in parentheses should have been inserted in the claims to

increase their intelligibility. This applies to both the preambles and characterising portions.

10. The application does not meet the requirements of Rule 5.1(a)(ii) PCT since documents **D1** and **D2** should have been cited in the description and the relevant background art disclosed therein should have been briefly discussed.

Re Item VIII

Certain observations on the international application

11. Claim 1 is not fully supported by the description (Article 6 PCT) since it is not clear which features shown in the figures or mentioned in the description do form the force application mechanism and the synchronizer cited in claim 1.

12. As can be seen from figures 5A to 5C and from the description on page 16, line 20, wings 208 form a parallelogram. Thus, claim 96 should be clarified (Article 6 PCT) by stating that **two wings (208)** define a parallelogram.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

13. The present application contains the following two inventions:

    a) the apparatus for controlling the deformation of an implant according to claim 1, followed by dependent claims 2 to 72, and
    b) the measurement appartus for taking measurements inside the body according to independent claim 90, followed by dependent claims 91 to 99.

    These two inventions are not so linked that they form a single general inventive concept. The single general inventive concept linking the inventions according to different claims can be defined by the common features of those claims. However, in the present case there are no common features in independent claims 1 and

90. Consequently, there is no common concept linking these claims. Thus, the application does not comply the requirements of unity of invention.

CLAIMS

1. Apparatus for controlling the deformation of an implant during deployment thereof, comprising:

a force application mechanism for applying deforming force to the implant, by axial motion of a force applicator against the implant; and

a restraint element positioning mechanism that positions a restraining element such that the deformation of the implant is controlled by restraint of the restraining element on allowable deformation; and

a synchronizer that synchronizers the motion of the restraining element and the force applicator, to achieve a desired deformation of the implant.

2. Apparatus according to claim 1, comprising a force input which receives continuous motion and couples it to the force application mechanism and to the restraint element positioning mechanism.

3. Apparatus according to claim 2, wherein said continuous motion is reciprocating motion.

4. Apparatus according to claim 3, wherein said restraint positioning mechanism moves said restraint element during one stroke of said reciprocating motion.

5. Apparatus according to claim 4, wherein said one stroke comprises a retraction of said restraint mechanism from said implant.

6. Apparatus according to any of claims 3-5, wherein said force application mechanism moves said force applicator during one stroke of said reciprocating motion.

7. Apparatus according to claim 6, wherein said one stroke comprises a retraction of said force applicator from said implant.

8. Apparatus according to claim 6, wherein said one stroke comprises an advance of said force applicator towards said implant.